

# GENERAL VITAMIN CORP

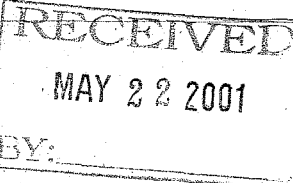
PO Box 1500 Chapel Hill NC 27516

919-929-5785 fax 919-929-2458

May 18, 2001

## CERTIFIED MAIL

Return Receipt Requested



Office of Nutritional Products, Labeling and Dietary Supplements  
HFS-800  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, SW  
Washington, D.C. 20204

To Whom it May Concern,

This letter is submitted pursuant to Section 406 (r)(6) of the Federal Food, Drug, and Cosmetic Act for the purpose of notifying the agency of statements being made in connection with the marketing of dietary supplements being distributed by this company.

The product name and the dietary ingredients for which the statement is being made is as follows:

### **ProstateForm**

|  |        |
|--|--------|
| Vitamin E (as d-alpha tocopheryl acetate)  | 200 IU |
| Zinc (as zinc monomethionine)  | 30mg   |
| Prostyn (Proprietary phytosterol-rich Complex of Pygeum [prunus africanum bark] And Avena sativa germ extract) | 250mg  |
| Amino Acid Triplex (Glycine [50mg], Alanine[50mg], Glutamine [50mg])   | 150mg  |
| Saw Palmetto (Serenoa repens fruit) (standardized 95%[76mg] fatty acids)                                       | 80mg   |
| Turmeric (Curcuma longa rhizome) (standardized 95%[47.5mg] curcumin)   | 50mg   |
| Pumpkin Seed Oil (Curcubita maxima) (naturally rich in alpha-linolenic acid)                                   | 50mg   |
| Lycopene (Lycopersicon esculentum fruit Extract)   | 5mg    |

Other ingredients: Gelatin, glycerin, soy oil and water

97S 0162

LET 8058

76047

### **LaxaForm**

World Algae Blend **100mg**

Phenalginate™ (Cystoseira canariensis from Canary Islands), Spirulina (Hawaiian Spirulina Platensis), Chlorella (Bulgarian Chlorella vulgaris) (broken cell), Cryptomonas (Asian), Red Kelp (Norwegian Palmaria palmata), Brown Kelp (Norwegian Laminaria digitata), Ulva (Asian Ulva rigida & Ulva fasciata), Red Seaweed (Irish Lithothamnium calcareum), Dulse (Mediterranean Rhodymenia palmata), Rockweed (American Ascophyllum nodosum)

Cascara Sagrada (Rhamnus purshiana bark) **50mg**

(standardized 25-30% [12.5-15mg] hydroxyanthracene derivatives [HAD])

Passionflower (Passiflora incarnata flower) **50mg**

(standardized 3.5-4% [1.75-2mg] flavonoids)

Senna (Cassia senna leaf) **5mg**

(standardized 5% [0.25mg] sennosides)

Other ingredients: Gelatin, glycerin, silica and water

The text of the statements that are being made in regards to the above stated products are listed below:

### **ProstateForm**

- prostateform
- nutritionally support healthy prostate function
- fortifying prostate health with optimal nutrition
- safe, natural and advanced support for the prostate gland
- biochemical support of the prostate
- bolster prostate wellness
- for optimal prostate health

**Laxaform**

- laxaform
  - nutritionally support healthy bowel function
  - for regular functionality
  - help restore our natural rhythms
  - for safe, natural relief and consistent results
  - health-boosting
  - support healthy bowel function, quickly, gently and effectively
- 

Sincerely,

GENERAL VITAMIN CORP.

*Megan Joslin*

Megan Joslin  
Product Development Coordinator